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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR             | ATTORNEY DOCKET NO. | CONFIRMATION NO.      |
|-----------------|-------------|----------------------------------|---------------------|-----------------------|
| 10/751,962      | 01/07/2004  | Takashi Suzuki                   | 2003_1924A          | 4501                  |
| 513             | 7590        | 05/12/2006                       |                     | EXAMINER              |
|                 |             | WENDEROTH, LIND & PONACK, L.L.P. |                     | SRIVASTAVA, KAILASH C |
|                 |             | 2033 K STREET N. W.              |                     |                       |
|                 |             | SUITE 800                        | ART UNIT            | PAPER NUMBER          |
|                 |             | WASHINGTON, DC 20006-1021        |                     | 1655                  |

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                           |                     |  |
|------------------------------|---------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>    | <b>Applicant(s)</b> |  |
|                              | 10/751,962                | SUZUKI ET AL.       |  |
|                              | <b>Examiner</b>           | <b>Art Unit</b>     |  |
|                              | Dr. Kailash C. Srivastava | 1655                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-9 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

1. Your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is assigned to Dr. Kailash C. Srivastava. In Art Unit 1655. To aid in correlating any papers for this application (i.e., USSN 10/313,643), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

### Claims Status

2. Claims 1-9 are pending.

### Election /Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I, consisting of claims 1-4 drawn to a method to make a yeast extract, classified under Class 4335, subclass 317, 820 or 917, for example.
- Group II, consisting of claim 5 drawn to a composition, classified under Class 436, subclass 69.9, for example.
- Group III, consisting of Claims 6-8 drawn to a method to make a protein, classified under Class 435, subclass 68, for example.
- Group IV, drawn to a kit, classified under Class 435, subclass 975, for example.

### Inventions are Independent Or Distinct

4. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I and III are unrelated to each other and inventions in Groups I and IV are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone

(MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I invention is directed to a method not requiring any synthesis with or without a cell. Invention method III encompassing claims 6-8, however, while still drawn to making a composition requires "synthesis". Similar relationship differences may be delineated for inventive groups I ad IV. Thus, each of the methods in invention grouped as inventions I and III or I and IV respectively have a different effect. Therefore, any of the methods claimed in inventions I or III, encompassing Claims 1-4 or 6-8 respectively or in Groups I and IV may not be practiced together.

Invention in Group II is related to invention in Group I as product made and process of making said product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed method to prepare the yeast extract may also be used to prepare any cell extract (e.g., for an enzyme assay). Likewise, the claimed biological composition may also be prepped by other means, e.g., autolyzing yeasts with art-known reagents.

Invention in Group II is related to invention in Group III as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case, the method of invention encompassed in Group III invention is accomplished with a number of commercially purchasable commodities (e.g., corn steep liquer). Similarly, it is well known in the pertaining art that the product of invention in Group II is applicable as a substrate or component in compositions for a variety of other applications (e.g., cell cultivation).

Invention in Group II is related to invention in Group IV and invention in Group III is related to invention in Group IV as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other if they are shown to be separately usable. In the instant case, the combination (i.e. comprising yeast extract for protein synthesis (i.e., kit) as claimed for patentability would, by itself be patentable even if the sub-combination (i.e., the yeast extract) was known and non-obvious, assuming that the prior art

does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combination has utility of its own because it will be applicable for not only as a substrate for protein synthesis, but also as a bioactive component for growing a variety of microorganisms as is well known in the pertaining art.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. For example, a search strategy for inventing in group I would require all the methods to disrupt a yeast cell to prepare a yeast cell extract. Search for Group II invention will have to include compositions comprising yeast extract without any other ingredient. Similarly, search for invention in group III would require the limitation to transform yeast extract into protein with simultaneous protein synthesis and dialysis. Likewise an invention in Group IV would require all the limitations pertaining to a kit. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- VI in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

5. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claims 1, 5-6 and 9 are generic claim. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(l).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1655  
(571) 272-0923

May 9, 2006

*R. Gitomer*

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200